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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/785,446 | 02/23/2004 | Lauren Otsuki | NOCAR.007A | 1443 |

20995 7590 02/11/2008

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| EXAMINER | |
|---|---|
| ROYDS, LESLIE A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 02/11/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/785,446 | OTSUKI ET AL. | |
| | Examiner | Art Unit | |
| | Leslie A. Royds | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**Upon further consideration of the claimed subject matter, the restriction requirement of June 22, 2007 has been VACATED in lieu of the following requirement, which supersedes the previous requirement of June 22, 2007.**

**Claims 1-34 are presented for examination.**

***Requirement for Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a pharmaceutical compositions comprising an adenosine A1 receptor antagonist (AA1RA) in combination with a beta-blocker or ACE inhibitor or angiotensin receptor blocker or an ACE inhibitor and angiotensin receptor blocker, classified in class 514, subclasses 262.1, 381, 412 or 423, for example, depending upon the compounds used.

II. Claims 10-13 and 26-34, drawn to a method for treating a cardiovascular disease comprising the administration of a pharmaceutical composition comprising an adenosine A1 receptor antagonist and a beta-blocker, classified in class 514, subclasses 262.1 or 423, for example, depending upon the compounds used.

III. Claims 14-16, drawn to a method for treating a cardiovascular disease or renal disease comprising the administration of a pharmaceutical composition comprising an adenosine A1 receptor antagonist in combination with an ACE inhibitor and/or angiotensin receptor blocker, classified in class 514, subclasses 262.1, 381 or 412, depending upon the compounds used.

IV. Claims 17-20, drawn to a method for treating alkalosis comprising the administration of an adenosine A1 receptor antagonist compound, classified in class 514, subclass 262.1, for example, depending upon the antagonist used.

V. Claims 21-25, drawn to a method for treating diabetic nephropathy comprising administering an adenosine A1 receptor antagonist compound, classified in class 514, subclass 262.1, for example, depending upon the antagonist used.

The inventions are distinct, each from the other, for the following reasons:

Inventions I and II-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the presently claimed pharmaceutical composition(s) of Invention I can be used in materially different processes of use, namely for the treatment of congestive heart failure or for the treatment of diabetic nephropathy, for example.

Inventions II-V are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. Please reference MPEP § 806.05(j). In the instant case, Inventions II-V are related because they require at least a step of administering an adenosine A1 receptor antagonist compound. However, the objective(s) of each of Inventions II through V are unique and distinct from one another such that the steps required for each single method are not required for the other methods. Specifically, each of Inventions II-V require an effective amount of the adenosine A1 receptor antagonist compound to achieve the claimed therapeutic purpose such that the amounts required to achieve each objective are distinct and unique to the desired objective. Accordingly, the modes of operation, functions and/or therapeutic effects of the methods are clearly distinct from one another, despite the fact that the Inventions are related solely on the basis of the administration of an adenosine A1 receptor antagonist compound. In view of the fact that the inventions as claimed do not

encompass overlapping subject matter and there is nothing of record to show them to be obvious variants, the inventions are properly held to be patentably distinct from one another.

Because these inventions are distinct for the reasons given above, they require a different field of search (see MPEP §808.02) and they have acquired a separate status in the art because of their recognized divergent subject matter, the requirement for examination purposes as indicated is proper.

***Election of Species Requirement***

This application contains claims directed to patentably distinct species of:

(1) pharmaceutical compositions of an adenosine A1 receptor antagonist (AA1RA) compounds in combination with a beta-blocker or an ACE inhibitor or an angiotensin receptor blocker or an ACE inhibitor and an angiotensin receptor blocker (claims 1-16);

(2) adenosine A1 receptor antagonist (AA1RA) compounds (claims 17, 20-21 and 23);

(3) cardiovascular diseases (claims 10-11 and 26-27);

(4) renal diseases (claims 14 and 16);

(5) alkalosis (claims 17-18); and

(6) diabetic nephropathic condition (claim 25).

The species are independent and/or distinct for the following reasons:

Regarding the species of compounds and combinations of compounds, the claimed AA1RA compounds encompass such a breadth of compounds that are structurally and/or chemically distinct from any one single other compound encompassed by the claims such that a comprehensive search of the patent and non-patent literature for any one such AA1RA compound would not necessarily result in a comprehensive search of any one or more of the other AA1RA compounds. Furthermore, in consideration of the number of possible combinations of products and the breadth of the genera of compounds with which the AA1RA compound may be used in combination, e.g., an ACE inhibitor, beta-

blocker or angiotensin receptor blocker, the disparate nature and breadth of compounds and combination products encompassed by the claimed genera precludes a quality examination on the merits, not only because a burdensome search would be required for the entire scope of the claim(s), but also because the consideration of the findings of such a search for compliance with the statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112, would be unduly onerous. In addition, though Applicant has recognized a common functionality to the claimed compounds, e.g., that they are capable of affecting the function of angiotensin and adenosine, it remains that the art does not necessarily recognize such a function as being shared by the entire claimed genera of compounds and, as a result, does not necessarily recognize their equivalency or interchangeability. Additionally, it also remains that the art may recognize an advantageous use for combining two types of claimed compounds that is not necessarily tied to their function in affecting angiotensin or adenosine function.

Regarding the species of diseases or conditions treatable via the modulation of cholinergic function, the species are independent or distinct because such diseases as recited in the present claims for which the AA1RA compound or AA1RA combination therapy must be therapeutically effective are each distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of active agent, frequency of treatment, etc.) and patient population such that a comprehensive search for the claimed compound in an amount effective to treat, for example, congestive heart failure, would not necessarily anticipate, suggest or render obvious the administration of the same or different compound in an amount effective to treatment an etiologically and pathophysiologically distinct disorder, such as diabetic nephropathy. Notwithstanding that Applicant may have established an underlying commonality to this genus of disorders, namely that each is treatable via the antagonism of adenosine A1 receptors, it remains that the art does not necessarily recognize such a shared characteristic as being common to the entire genera of diseases encompassed by the claims, nor does the art necessarily recognize each as amenable to the same type of pharmacologic therapy. Each is

considered patentably distinct from the others because the patient populations, dosage amounts and therapeutic protocol for treating the claimed disorders are each unique to the type of disorder being treated such that a comprehensive search for the claimed compound in an amount effective for the treatment of a particular disorder in the prior art would not necessarily encompass a comprehensive search of the patent or non-patent literature for the claimed compound in an amount effective for the treatment of any one or more other disorders.

***Election of Invention I requires Applicant to make the following species elections:***

Election of a single disclosed combination of compounds selected from:

(i) an adenosine A1 receptor antagonist (AA1RA) and a beta-blocker (claim 1);

(ii) an AA1RA and an ACE inhibitor (claim 3);

(iii) an AA1RA and an angiotensin receptor blocker (ARB) (claim 4); or

(iv) an AA1RA and an ACE inhibitor and an ARB (claim 5).

Should Applicant elect (i), then Applicant is required to further elect:

a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claims 8-9) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claims 8-9; **and**

a **single disclosed specie** of beta-blocker from those specifically claimed (see, e.g., present claim 2) **or** a generic beta-blocker not specifically claimed in present claim 2.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is specifically recited in claims 8-9, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which

belongs to generic structural formula (I)).

Should Applicant elect (ii), then Applicant is required to further elect:

a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claims 8-9) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claims 8-9; **and**

a **single disclosed specie** of ACE inhibitor from those specifically claimed (see, e.g., present claim 6) **or** a generic ACE inhibitor not specifically claimed in present claim 6.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is specifically recited in claims 8-9, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which belongs to generic structural formula (I)).

Should Applicant elect (iii), then Applicant is required to further elect:

a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claims 8-9) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claims 8-9; **and**

a **single disclosed specie** of ARB from those specifically claimed (see, e.g., present claim 7) **or** a generic ARB not specifically claimed in present claim 7.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is specifically recited in claims 8-9, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which

belongs to generic structural formula (I)).

Should Applicant elect (iv), then Applicant is required to further elect:

a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claims 8-9) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claims 8-9; **and**

a **single disclosed specie** of ACE inhibitor from those specifically claimed (see, e.g., present claim 6) **or** a generic ACE inhibitor not specifically claimed in present claim 6; **and**

a **single disclosed specie** of ARB from those specifically claimed (see, e.g., present claim 7) **or** a generic ARB not specifically claimed in present claim 7.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is specifically recited in claims 8-9, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which belongs to generic structural formula (I)).

***Election of Invention II requires Applicant to make the following species elections:***

(v) Election of a **single disclosed specie** of cardiovascular disease from those specifically claimed (see, e.g., claim 11 or 27) **or** a generic cardiovascular disease not specifically claimed in present claim 11 or 27; **and**

(vi) Election of a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claims 8-9 or 30-32) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claims 8-9 or 30-32; **and**

(vii) Election of a **single disclosed specie** of beta-blocker from those specifically claimed (see, e.g., present claim 33) **or** a generic beta-blocker not specifically claimed in present claim 33.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is specifically recited in claims 8-9 or 30-32, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which belongs to generic structural formula (I)).

***Election of Invention III requires Applicant to make the following species elections:***

(viii) Election of a single disclosed combination of compounds selected from:

(a) an AA1RA and an ACE inhibitor (claim 3);

(b) an AA1RA and an angiotensin receptor blocker (ARB) (claim 4); or

(c) an AA1RA and an ACE inhibitor and an ARB (claim 5).

Should Applicant elect (a), then Applicant is required to further elect:

a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claims 8-9) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claims 8-9; **and**

a **single disclosed specie** of ACE inhibitor from those specifically claimed (see, e.g., present claim 6) **or** a generic ACE inhibitor not specifically claimed in present claim 6.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is specifically recited in claims 8-9, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which belongs to generic structural formula (I)).

Should Applicant elect (b), then Applicant is required to further elect:

a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claims 8-9) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claims 8-9; **and**

a **single disclosed specie** of ARB from those specifically claimed (see, e.g., present claim 7) **or** a generic ARB not specifically claimed in present claim 7.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is specifically recited in claims 8-9, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which belongs to generic structural formula (I)).

Should Applicant elect (c), then Applicant is required to further elect:

a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claims 8-9) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claims 8-9; **and**

a **single disclosed specie** of ACE inhibitor from those specifically claimed (see, e.g., present claim 6) **or** a generic ACE inhibitor not specifically claimed in present claim 6; **and**

a **single disclosed specie** of ARB from those specifically claimed (see, e.g., present claim 7) **or** a generic ARB not specifically claimed in present claim 7.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is specifically recited in claims 8-9, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which belongs to generic structural formula (I)).

(ix) Election of a **single disclosed disease** selected from:

(d) cardiovascular disease; or

(e) renal disease.

Should Applicant elect (d), then Applicant is required to further elect:

a **single disclosed specie** of cardiovascular disease from those specifically claimed (see, e.g., present claim 15) **or** a generic cardiovascular disease not specifically claimed in present claim 15.

Should Applicant elect (e), then Applicant is required to further elect:

a **single disclosed specie** of renal disease from those specifically claimed (see, e.g., present claim 16) **or** a generic renal disease not specifically claimed in present claim 16.

***Election of Invention IV requires Applicant to make the following species elections:***

(x) Election of a **single disclosed specie** of alkalosis from those specifically claimed (see, e.g., claim 18) **or** a generic type of alkalosis not specifically claimed in present claim 18; **and**

(xi) Election of a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claim 20) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claim 20.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is

specifically recited in claim 20, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which belongs to generic structural formula (I)).

***Election of Invention V requires Applicant to make the following species elections:***

(xii) Election of a **single disclosed specie** of diabetic nephropathic condition to be treated (see, e.g., claim 25) **or** a generic type of diabetic nephropathic condition not specifically claimed in present claim 25; **and**

(xiii) Election of a **single disclosed specie** of adenosine A1 receptor antagonist from those specifically claimed (see, e.g., present claim 23) **or** a generic adenosine A1 receptor antagonist not specifically claimed in present claim 23; **and**

Applicant is further required in reply to this action, should he elect the invention of Group V, to elect embodiments of this invention in which (f) an additional agent is **NOT** present or (g) an additional agent **IS** present (i.e., see present claim 24). If Applicant elects embodiments wherein an additional agent is present in the elected embodiment, then Applicant is required to further elect a single disclosed specie of agent for examination on the merits consistent with the following instructions:

If Applicant elects an embodiment wherein a protein kinase C inhibitor is present as the additional agent, election of a **single disclosed specie** of protein kinase C inhibitor must be made.

If Applicant elects an embodiment wherein an inhibitor of tissue proliferation is present as the additional agent, election of a **single disclosed specie** of tissue proliferation inhibitor must be made.

If Applicant elects an embodiment wherein an antioxidant is present as the additional agent, election of a **single disclosed specie** of antioxidant must be made.

If Applicant elects an embodiment wherein an inhibitor of glycosylation is present as the additional agent, election of a **single disclosed specie** of glycosylation inhibitor must be made.

If Applicant elects an embodiment wherein an endothelin B receptor inhibitor is present as the additional agent, election of a **single disclosed specie** of endothelin B receptor inhibitor must be made.

NOTE: Should Applicant elect a specie of adenosine A1 receptor antagonist that is specifically recited in claim 23, Applicant **must identify to which structural formula it belongs** (e.g., specie X, which belongs to generic structural formula (I)).

Applicant is cautioned that the election of a particular specie compound, disease and/or specific combination of compounds, wherein the elected specie(s) is/are not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

Currently, claims 1-34 are generic.

**Applicant is advised that a reply to this requirement is REQUIRED to include an (1) identification of the invention for examination on the merits, (2) identification of the single disclosed species elected consonant with the requirements set forth *supra* and (3) a structural depiction of the elected adenosine A1 receptor antagonist (including identification of each and every substituent in the elected compound), that is elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to

additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the

limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

January 30, 2008

2/2/08
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER